UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/562,852	04/19/2006	Ehud Gazit	31230	6440

7590 06/04/2008

Martin D Moynihan
Prtsi Inc
PO Box 16446
Arlington, VA 22215

EXAMINER	
DUTT, ADITI	

ART UNIT	PAPER NUMBER
1649	

MAIL DATE	DELIVERY MODE
06/04/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/562,852	GAZIT, EHUD	
	Examiner	Art Unit	
	Aditi Dutt	1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/20/07*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,12,40,72-79,81-102,118,141,148,155-159* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1,12,40,72-79,81-102,118,141,148,155-159* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, 12, 72-101, drawn to a peptide, a pharmaceutical composition comprising the peptide thereof, comprising an amino acid sequence X-Y or Y-X.

Group II, claim(s) 40, drawn to a method of treating or preventing an amyloid associated disorder comprising providing the individual a peptide of amino acid sequence of X-Y or Y-X.

Group III, claim(s) 102, drawn to a nucleic acid construct comprising a polynucleotide segment.

Group IV, claim(s) 118, 141, drawn to an antibody or an antibody fragment, a pharmaceutical composition comprising thereof, comprising an antigen recognition region.

Group V, claim(s) 148, drawn to a method of treating or preventing an amyloid associated disorder comprising providing the individual an antibody or an antibody fragment.

Group VI, claim(s) 155-158, drawn to a peptide or a cyclic peptide, where C is a chiral carbon having D configuration.

Group VII, claim(s) 159, drawn to a method of treating or preventing an amyloid associated disorder comprising providing the individual a peptide, where C is a chiral carbon having D configuration.

It is noted that there is a typo in stating claims "41-73 (canceled)", because claims 72 and 73 are not canceled. Appropriate correction is requested.

2. The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group I recites the special technical feature of a peptide, a pharmaceutical composition comprising the peptide thereof, comprising an amino acid sequence X-Y or Y-X, which is not required by the other products of Groups III, IV and VI.

Group II recites the special technical feature of method of treating or preventing an amyloid associated disorder comprising providing the individual a peptide of amino acid sequence of X-Y or Y-X, which is not required by the other methods of Groups V and VII.

Group III recites the special technical feature of nucleic acid construct comprising a polynucleotide segment, which is not required by the other products of Groups I, IV and VI.

Group IV recites the special technical feature of an antibody or an antibody fragment, a pharmaceutical composition comprising thereof, comprising an antigen recognition region, which is not required by the other products of Groups I, III and VI.

Group V recites the special technical feature of treating or preventing an amyloid associated disorder comprising providing the individual an antibody or an antibody fragment, which is not required by the other methods of Groups II and VII.

Group VI recites the special technical feature of a peptide or a cyclic peptide, where C is a chiral carbon having D configuration, which is not required by the other products of Groups I, III and IV.

Group VII recites the special technical feature of treating or preventing an amyloid associated disorder comprising providing the individual a peptide, where C is a chiral carbon having D configuration, which is not required by the other methods of Groups II and V.

3. A further restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

The applicant is required to elect *one* sequence for prosecution, from one of the following groups:

Please refer to claims 12 and 81 for a complete list of the sequences.

4. The inventions listed as Groups 1-55 do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: In the instant case, the different inventions of Groups (1-55) are unique peptide molecules of different lengths and are composed of different amino acids. Accordingly, each of the different protein sequences are not so linked under PCT Rule 13.1 and are thus placed in thirteen different inventive groups numbered 1-55. Searching all of the sequences in a single patent application would provide an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches. Furthermore, each of the sequences represents a different peptide with unique and diverse functional features.

Note: This is a Restriction requirement, not an Election of species. In order to be fully responsive, Applicant must select one from Inventions I-VII and one from groups 1-55.

Species Election

A) Number of amino acid residues

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a) At least 2 or not more than 15 amino acids

b) At least 4 amino acids including at least 2 serine residues

c) At least 3 amino acids and one amino acid is polar uncharged

d) 2 amino acids

e) 3 amino acids

The claims are deemed to correspond to the species listed above in the following manner:

Claims 1, 40, 72, 82, 95-97, 99

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above peptide sequences of different lengths and comprising different amino acids, determine distinct structure and function to the peptide molecule that involves extensive search burden. For example, the special technical feature of (a) is At least 2 or not more than 15 amino acids. This special technical feature is not shared by the other species.

B) "Y" amino acid

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

f) Polar uncharged

g) Naturally occurring

h) Synthetic

The claims are deemed to correspond to the species listed above in the following manner: Claims 73, 75, 77, 83, 85, 87.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above amino acids will determine distinct structural and functional features to the peptide. For example, the special technical feature of polar uncharged amino acid is not shared by the other amino acids.

C) Polar uncharged amino acid

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicant elected the 'polar uncharged amino acid' as the species of Y amino acid, applicant is further required to select a more specific polar uncharged amino acid.

i) Serine

j) Threonine

k) Asparagine

l) Glutamine

The claims are deemed to correspond to the species listed above in the following manner: Claims 73, 83

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above amino acids will determine distinct structural and functional features to the peptide. For example, the special technical feature of Serine is not shared by the other amino acids.

D) Naturally occurring amino acid

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

If applicant elected the 'Naturally occurring' as the species of β-sheet breaker amino acid, applicant is further required to select a more specific naturally occurring amino acid.

m) Proline

n) Aspartic acid

o) Glutamic acid

p) Glycine

q) Lysine

r) Serine

The claims are deemed to correspond to the species listed above in the following manner: Claims 76, 86

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above amino acids will determine distinct structural and functional features to the peptide. For example, the special technical feature of proline is not shared by the other natuarally occurring amino acids.

E) Location of β-sheet breaker amino acid (Y) in sequence

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

s) Upstream to X-Y

t) Downstream to X-Y

The claims are deemed to correspond to the species listed above in the following manner: Claims 90, 91

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above positions of the β-sheet breaker amino acid (Y) will determine distinct structural and/or functional characteristics to the peptide. For example, the special technical feature of upstream location to X-Y is not shared by the downstream location to X-Y.

F) Positively charged amino acid

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

u) Lysine

v) Arginine

The claims are deemed to correspond to the species listed above in the following manner: Claim 93.

Claim 92 is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above amino acids will determine distinct structural and functional features to the peptide. For example, the special technical feature of lysine is not shared by arginine.

G) Negatively charged amino acid

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

w) Aspartic acid

x) Glutamic acid

The claims are deemed to correspond to the species listed above in the following manner: Claim 94.

Claim 92 is generic.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: Each of the above amino acids will determine distinct structural and functional features to the peptide. For example, the special technical feature of aspartic acid is not shared by glutamic acid.

5. Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

6. In response to this Office Action/Election requirement, applicant must elect one from Groups I-VII and 1-55 (amino acid sequence), and must additionally elect a species of number of amino acid residues, “Y” amino acid, naturally occurring amino

acid, location of β-sheet breaker amino acid (Y) in sequence, positively charged amino acid and negatively charged amino acid.

7. Applicant is advised that in order for the reply to this requirement to complete it must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. 1.143).

8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48 (b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 C.F.R. 1.48(b) and by the required under 37 C.F.R. 1.17(I).

Notice of Rejoinder

9. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

10. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aditi Dutt whose telephone number is 571-272-9037. The examiner can normally be reached on M-F.

12. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AD
24 May 2008

/Jeffrey Stucker/

Supervisory Patent Examiner, Art Unit 1649